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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,194	11/17/2003	Radislav Alexandrovich Potyrailo	RD26349-3	9351

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EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,194

Applicant(s)

POTYRAILO ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 25-50 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

1. Amendment filed on 05/18/06 is acknowledged. Claims 25-50 are pending in the application.

Response to Amendment

2. In response to the amendment the examiner slightly modifies rejections under 35 U.S.C. 112, first paragraph and over the prior art.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is not clear, how a relative location of the chemical species in the content of the capillary can be an indication of their ground location? Relative location will always be a relative location, unless there is a reference point in the ground location, comprising reference chemical species, which can provide a reference point within the capillary. Such reference point comprising reference chemical species is not disclosed in the specification. Another way to define ground location would be determining time at which the chemical species diffused into the capillary and defining their flow rate through the capillary, which also are not disclosed in the specification. Therefore, the method recited in the claims is not enabled by the present specification.

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4. If claims 25-50 were enabled by the specification, i.e. the specification disclosed the ways to measure time of diffusion of chemical species into the capillary or had a reference species at the same ground location, the claims could have been rejected under 35 U.S.C. 103(a) in the following manner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. **Claims 25-39, 46 and 48-50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess (US 5,434,084).

Burgess discloses an apparatus and method for detecting a presence, determining a location, and quantifying an amount of chemical analytes, comprising providing a capillary with a permeable wall (8) to the analytes, delivering a fluid comprising a reagent, which is capable to selectively interact with analytes (col. 2, lines 63-68), into the capillary, and transferring a content of the capillary to an optical detector (Figure 1, col. 5, lines 50-56 and col. 6, lines 10-15), with the detector employing various optical methods. In one embodiment the optical methods utilized are UV, visible light or IR spectroscopy (col. 3, lines 47-49). In another embodiment the optical methods are scattering and/or reflective index measurements (col. 4, lines 54-60). See also col. 5, lines 17-20: “the device is compatible with numerous spectroscopic techniques including, but not limited to, absorbance, luminescence, chemiluminescence, fluorescence and light scattering for the analyte modulation of the optical signal”. The concentration of the analyte is determined from the response of the optical detector. The permeable wall of the capillary comprises materials selected from “rubber, porous polypropylene, such as Celgard X-20 or X-10, and porous teflon. Each of the semipermeable membranes has pore sizes that control the movement of molecules based on the size of the molecules. For example, the pore size may range from about $0.05\ \mu\text{m}$ [50 nm] to about $10\ \mu\text{m}$. The permeable membrane may also be an ion exchange membrane to separate analytes by size and charge. More specifically, anion exchange membranes include aminated polystyrene, divinyl benzene, aminated polypropylene, aminated polyethylene, other aminated polymers and other polymers with functional groups, such as trimethyl amine, ethyl dimethyl amine, and dimethyl ethanol amine. Cation exchange membranes include Nafion.RTM., and sulfonated polystyrene, polyacrylates and polypropylene. The ion exchange membrane can also comprise radiation grafted polymers such as polypropylene, polyethylene, and polystyrene, with various charged functional groups. The choice of the semipermeable or ion exchange membrane depends upon the molecular size and charge characteristics of the analyte or analytes to be detected” (col. 7, line 68 and col. 8, lines 1-22). In one embodiment, Figure 4, “a frit [porous glass or ceramics] may be employed to prevent plugging of the sample capillary” (col. 12, lines 60-62), which corresponds to the subject matter of claims 9 and 10. Optical fibers are selected according to the application. “Fibers are available that cover most of the spectral region of the

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electromagnetic radiation spectrum from the **ultraviolet (220 nm) to the near-infrared**", which is in the range recited in claims 7 and 23 (col. 7, lines 17-20). "Microporous hollow fiber membranes [capillaries] were made of polypropylene and had **400 μm** [0.4 mm] internal diameters [claims 13 and 14], **0.03 μm** [30 nm] average pore size [claims 11 and 12], 40% porosity and **25 μm** wall thickness [claims 15 and 16] (Hoechst Celanese, Charlotte, N.C., Model Celgard X-20) (Example 1, col. 13, lines 49-54). Burgess emphasizes, "by continuously renewing the reagent in the probe, the response and recovery times are improved over static reagent sensors. The reagent flow in mixing within the probe, creates a steep gradient in the chemical potential of the analyte across the permeable membrane interface, which results in a rapid steady state concentration" (col. 9, lines 3-5) and "the inventive flow optrode can adjust the sensitivity and dynamic range to the concentration of the analyte or changes in concentration of the analyte by varying the flow rate, the reagent composition, or by **operating in a stop flow mode**. Therefore, the inventive device and the inventive method for using the inventive device offer significant advantages over previously developed optrodes" (col. 10, lines 19-26). The probe is capable of being used in different environment, including soil or during combinatorial synthesis.

While Burgess does not specifically teach a method for determining location of the chemical species at the ground, it would have been obvious for any person of ordinary skill in the art to apply Burgess' method for detecting the chemical species in the soil and defining their location by using reference chemical species in this location.

6. **Claims 40-45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess in view of abundant prior art, e.g. Miller et al. (US 4,666,672), Klainer et al. (US 5,059,790), Tabacco et al. (US 5,268,972), Mohr et al. (EP 928,966 A1), Donner et al. (ACS Symposium), Bakaltcheva et al. (Anal. Chim. Acta), Sano et al. (Anal. Sic.), Gladilovich et al. (Zh. Anal. Khimii).

While Burgess does not specifically disclose analytes (chemical species) recited in the claims indicated above, he repeatedly emphasizes that any analytes, which can chemically react with the reagents "to create a reaction product that modulates electromagnetic radiation differently from the unreacted reagent" (col. 2, lines 63-67, col. 4, lines 64-69 and col. 7, lines 1-9)) are potential analytes for the apparatus disclosed. Moreover, he mentions that "the probe has

multiple analyte capability because the same probe can be used for a variety of different analytes simply by changing the nature and/or concentration of the reagent in the reservoir” (col. 5, lines 23-28).

Miller discloses optrode for detecting halogenated hydrocarbons, including “chloroform, methylchloroform, sym-tetrachloroform, phenylchloroform, carbon tetrachloride, dichloromethane, trichloroethylene, 1,1,2-trichloroethane and the like” (col. 4, lines 58-62).

Klainer discloses reservoir fiber optic chemical sensors for detecting various analytes, including trichloroethylene (TCE) (col. 6, line 51).

Tabacco discloses “aromatic hydrocarbon optrodes for groundwater monitoring applications”, including detecting aromatic compounds, such as benzene, toluene (PhMe), ethylbenzene and xylene (col. 3, lines 50-52).

Mohr teaches detecting cycloaliphatic, primary, secondary or tertiary aliphatic and aromatic amines, including pyridine and aniline, by fluorescence chemical sensors (Abstract, page 2, par. [0012], Tables 1-3, pages 14, 15, 16).

Donner and Bakaltcheva disclose “multi-analyte explosive detection using a fiber optic biosensor”, including detecting trinitrobenzole (TNT) (Abstract).

Sano teaches “fluorometric determination of aromatic aldehydes with 1,4-dimethyl-3-carbamoylpyridinium chloride”, including detection of benzaldehyde, furfural and 4-methoxybenzaldehyde (Abstract).

Gladilovich teaches “fluorometric determination of aromatic aldehydes with 1,2-diaminobenzene”, including detection of benzaldehyde and its derivatives (Abstract).

It would have been obvious for anyone of ordinary skills in the art to modify Burgess’ apparatus for detecting analytes recited in claims 17-22, 24, because, as numerous references demonstrate these are important chemicals for analysis (toxins, explosives, etc.), which are conventionally analysed by optical methods, i.e. with conventional optrodes (halogenated hydrocarbons, polynitroaromatic hydrocarbons, mono-substituted benzene, pyridine), as disclosed by Miller, Klainer, Tabacco, Mohr, Donner and Bakaltcheva, or fluorometrically by reacting with reagents which give specific optical characteristics, as taught by Sano and Gladilovich, while Burgess indicated the advantages of his apparatus versus conventional optrodes and standard fluorescence methods.

Response to Arguments

7. Applicant's arguments filed 05/18/06 have been fully considered but they are not persuasive. The amendment to the claims does not cure the lack of enablement for the instant method, as indicated in the present Office action. The specification does not disclose any ways to relate the relative locations of the chemical species in the content of the capillary to their ground locations. Moreover, if diffusion of the chemical species into the capillary takes time, and the time is different for different species, determining their ground locations becomes even more problematic.

Regarding rejection over the prior art, Burgess specifically indicates that “the inventive flow optrode can adjust the sensitivity and dynamic range to the concentration of the analyte or changes in concentration of the analyte by varying the flow rate, the reagent composition, or by **operating in a stop flow mode**” (col. 10, lines 19-26), which answers the Applicants’ concern regarding sufficient residence time of the reagent flow in the capillary to allow permeating the chemical species through the capillary walls.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

7/3/06



**YELENA GAKH
PRIMARY EXAMINER**